MinXray, Inc.
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

July 8, 2020

Re: K201575
Trade/Device Name: CMDR 2C (Multiple Models)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB, LLZ
Dated: June 10, 2020
Received: June 11, 2020

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201575

Device Name
CMDR 2C (Multiple Models)

Indications for Use *(Describe)*
Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: 510(k) Number K201575

MinXray, Inc.
3611 Commercial Avenue
Northbrook, Illinois 60062, USA
Toll Free 1-800-221-2245 (USA & Canada)
Date Prepared: June22, 2020
Contact: Keith Kretchmer, President

1) **Identification of the Device:**
Trade/Device Name: CMDR 2C (Multiple Models)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Codes: IZL, MQB, and LLZ.
Common/Usual Name: Digital Mobile Diagnostic X-Ray System

2) **Equivalent legally marketed device**: **K191451, MinXray, Inc.**
Trade/Device Name: CMDR 2CW (Multiple Models)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Codes: IZL, MQB, and LLZ.
Common/Usual Name: Digital Mobile Diagnostic X-Ray System

3) Reference device (We employ these cleared devices without modification):
Trade/Device Name: K153058 CareView 1500C/CareView 1500L X-ray Flat Panel Detectors;
Manufacturer: CareRay Digital Medical Systems Co., Ltd
Regulation Number: 21 CFR 892. 1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB

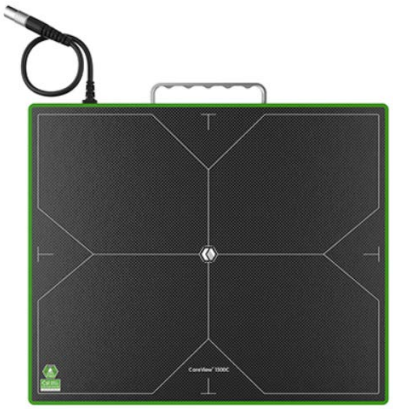
4) **Indications for Use (intended use):** These digital radiographic systems are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammographic use.

5) **Description of the Device**: This represents the straightforward combination of three devices:
One of three cleared MinXray Portable HF X-ray generators:
   a) HF120/60H PowerPlus cleared in K040046, (and in K141885) OR
   b) HF100H+ cleared in K052721 OR
   c) HF1202 PowerPlus cleared in K153059.
   d) Plus: A 510(k) cleared (K153058) Digital X-Ray Receptor Panel CareView 1500C X-ray Flat Panel Detector.
   e) PLUS: the dicomPACS® software package (Same as our predicate).

The x-ray generators are portable units which operate from 120/240V 50-60~ AC. The generator unit utilizes a high frequency inverter and can be mounted to a tripod or support arm. The usual safety precautions regarding the use of x-rays must be observed by the operator. The digital panel features the Careray flat panel technology in a sleek and compact unit. The portable panel provides digital X-ray image capture for a wide range of applications. The lightweight design, generous imaging area, and fast processing times of the detector make it easy to capture high quality diagnostic images for routine diagnosis, as well as challenging trauma and bedside exams. It's a portable solution for a faster, more streamlined approach to digital radiography. The only difference between this modified device and our predicate devices is the model number of the digital x-ray receptor panel. The predicate panel can communicate either by wireless or wired connection. The subject device communicates by Ethernet only.

6) Substantial Equivalence Chart

Characteristic	Predicate: K191451 CMDR 2CW (Multiple Models)	CMDR 2C (Multiple Models)
Intended Use:	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography	SAME
Configuration	Mobile System with digital x-ray panel and image acquisition computer	SAME
Computer	Dell Precision M3530 or Dell Latitude 7424 (ruggedized)	Dell Precision M3530 or Dell Latitude 7424 (ruggedized)
X-ray Generator(s) (All made by Mikasa X-Ray)	HF120/60H PowerPlus (K040046) or HF100H+ (K052721) or HF1202H PowerPlus (K153059)	SAME
Basic Generator Characteristics	120 VAC Line operated: HF120/60H PowerPlus™ produces up to 120 kVP and 2.4 kW peak HF100H+: up to 100 kVp and 2 kW peak HF1202H PowerPlus: up to 120 kVp up to 3.0 kW peak	SAME
Collimator	Collimare LED Collimator	Collimare LED Collimator
Generator Photo(s) The same generators will be used for the modified device	HF120/60HPPWV 	HF100H+ 	HF1202 H 
Digital X-ray Panel Supplied	K150929 CareView 1500Cw X-ray Flat Panel Detector manufactured by CareRay	K153058 CareView 1500C X-ray Flat Panel Detector manufactured by CareRay
Panel Performance	Pixel Pitch 154 µm 2304 × 2816 pixels Size 14” x 17” (Cleared in K150929) CsI Scintillator Spatial Resolution Min. 3.3 line pair/mm A/D Resolution: 16 bit, 65536 grayscale MTF - 65% @ 1 lp/mm DQE Performance: > 65% @ 0 lp/mm	Pixel Pitch 154 µm 2304 × 2816 pixels Size 14” x 17” (Cleared in K153058) CsI Scintillator Spatial Resolution Min. 3.3 line pair/mm A/D Resolution: 16 bit, 65536 grayscale MTF - 65% @ 1 lp/mm DQE Performance: > 65% @ 0 lp/mm Note: This panel was cited as the predicate in K150929. The panels are identical except for the method of image communication to the host.
Panel Communication	IEEE 802.11a/b/g/n (2.4 GHz /5 GHz)	Gigabit Ethernet

Characteristic	Predicate: K191451 CMDR 2CW (Multiple Models)	CMDR 2C (Multiple Models)
Panel Power Source	DC Adapter or Lithium Ion rechargeable battery	DC Adapter or Lithium Ion rechargeable battery
Panel Interface	Ethernet or Wi-Fi wireless	Ethernet only
Meets US Performance Standard	YES	YES
PACS software	dicomPACS® (Cleared with the Toshiba panels in K141440)	SAME
Power Source	120 V 50/60 Hz AC 20 amp	SAME
Digital Panel Power Source	120 V 50/60 Hz AC or Lithium Ion Rechargeable Battery.	SAME
Digital Panel		
Model Details	(All models use O&R Imaging Software with the Careray Digital Panel and a Dell Laptop) (Five Models) Model Details: CMDR.CW.120.60.S for Dell Precision or CMDR.CW.120.60.R for Dell Latitude Laptop or equivalent Uses HF120/60HPPWV Generator with CareView 1500Cw and O&R Imaging Software CMDR.CW.100.S for Dell Precision or CMDR.CW.100.Rfor Dell Latitude Laptop or equivalent Uses HF100H+ Generator with CareView 1500Cw and O&R Imaging Software. CMDR.CW.1202.S for Dell Precision Laptop or equivalent or CMDR.CW.1202.R for Dell Latitude Laptop or equivalent Uses HF1202 Generator with CareView 1500Cw and O&R Imaging Software CMDR 2CW-MIL (Uses Dell Latitude 7424 or equivalent with the HF120/60HPPWV Generator with CareView 1500Cw and O&R Imaging Software	(All models use O&R Imaging Software with the Careray Digital Panel and a Dell Laptop) (Five Models) Model Details: CMDR.C.120.60.S for Dell Precision or CMDR.C.120.60.R for Dell Latitude Laptop or equivalent Uses HF120/60HPPWV Generator with CareView 1500Cw and O&R Imaging Software CMDR.C.100.S for Dell Precision or CMDR.C.100.Rfor Dell Latitude Laptop or equivalent Uses HF100H+ Generator with CareView 1500Cw and O&R Imaging Software. CMDR.C.1202.S for Dell Precision Laptop or equivalent or CMDR.C.1202.R for Dell Latitude Laptop or equivalent Uses HF1202 Generator with CareView 1500Cw and O&R Imaging Software CMDR 2C-MIL (Uses Dell Latitude 7424 or equivalent with the HF120/60HPPWV Generator with CareView 1500Cw and O&R Imaging Software

7) **The technological characteristics, including design, materials, composition, and energy source, are substantially the same,** so there are no issues impacting safety and effectiveness.
Safety and Effectiveness, comparison to predicate device. The results of bench testing indicate that the new devices are as safe and effective as the predicate devices. Proper system operation is fully verified upon installation. We verified that the modified combination of components worked properly and produced diagnostic quality images as good as our predicate generator/panel combination. NO HARDWARE OR SOFTWARE MODIFICATIONS TO ALREADY CLEARED DEVICES WERE REQUIRED TO CREATE THESE NEW MODELS. The main difference from the predicate device is the addition of the CareView 1500 CW flat-panel detector, that replaces the Toshiba and Perkin-Elmer digital imagers used with the predicate system.

8) **Summary of non-clinical testing:** Prototype systems covering all generator/panel combinations were assembled and tested. First the dicomPACS® software was installed on the Dell Inspiron laptop computer. The proper installation was verified by running the software. A Wi-Fi connection was confirmed between the PerkinElmer panel and the Dell laptop. The panel was confirmed to be charged and turned on. Then the MinXray HF portable generator was turned on. The MinXray portable X-ray generator was set to generate an exposure. The generator was aimed at the PerkinElmer panel, and a radiographic phantom was placed on the panel. Several test exposures showed that the system was operating properly. No modifications were necessary to any of the hardware or software other than changing the digital panel. The completed system complies with DHHS radiation safety standards currently in effect, and has undergone testing for compliance with UL 60601-1 (2005) (Electrical medical device safety), IEC 60601-1-2 (2007) (Electromagnetic Compatibility). Additionally, the HF1202H PowerPlus generator meets IEC 60601-2-54: Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy. The other generators were designed and cleared prior to the issuance of this standard. We verified software compatibility with the new CareView Cw digital panel. The risks and hazardous impacts of the device modification were analyzed by FMEA methodology. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented as part of product design. The overall assessment concluded that all identified risks and hazardous conditions were successfully mitigated and accepted.
We employed the i.b.a. Test Device DIGI-13, a device for quality tests at CR and DR systems (e.g. for acceptance tests according to DIN V 6868-58 and constancy tests according to DIN 6868-13) to obtain images from both the predicate and the new digital panel. All panel/generator combinations were tested. The images were evaluated and found to be of diagnostic quality.
In recognition of the FDA Guidance on Cybersecurity, we added Cybersecurity precautions to our labeling and obtained Cybersecurity information from our DICOM software supplier Oehm Und Rehbein.

9) **Summary of clinical testing:** Clinical testing was not required to establish substantial equivalence.

10) **Conclusion: After analyzing bench and clinical tests, it is the conclusion of MinXray Inc. that the modified Digital Diagnostic X-Ray Systems are as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.**